UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,114	08/18/1998	IAN ASHLEY PRICE	P8129-8004	7439

6449 7590 05/31/2007

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
05/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	09/125,114	PRICE, IAN ASHLEY	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-47 and 52-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-47 and 52-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicant's amendemnts and remarks submitted March 5, 2007 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 39-47, 52-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armitage et al US Patent 5,696,165.

3. The scope of the instant claims are directed to solid compressed composition comprising racemic ibuprofen in the form of sodium salt in amount of at least 35% by weight of the composition, a compressible filler combined with a disintegrant, and sodium carbonate in amount of about 3-20%. The claimed composition also contains various functional limitations, which are either attributed to its intended use or its process of making. For example the recitation of "non-effervescent" dosage form (in claim 74) is viewed as an intended use limitation because once the individual components of the instant claims are described in a prior art composition, the prior art composition is expected to provide the claimed intended use.

4. The limitations directed to compression force and crushing strength are also directed to the process of making the dosage form. Examiner states composition claims that are drafted as "product by process" are not limited to the manipulations of the recited steps, only the structure

implied by the steps. (see MPEP 2113). "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

5. Thus, Applicant is placed on notice that the recited functional limitations do not appear to affirmatively limit the scope of the claimed composition.

6. Armitage teaches solid compositions comprising sodium salt of S(+) ibuprofen and sodium carbonate in the form of granules (see col. 16, example 18). The formulation of Armitage contains 16.5% ibuprofen salt and 4.6 % of sodium carbonate. The granule formulations of Armitage can have up to about 99% ibuprofen, therefore, Armitage teaches the concentrations of the instant claims. (see col. 22, lines 24-37). Armitage further teaches the use of fillers and disintegrants in his formulations including lactose, croscarmellose, cyclodextrin, etc...(see col. 22, lines 20-40; col. 2, line 66-col 3, line 43). Armitage further teaches film coating of his oral compositions (see col. 15-17). The particular Armitage's granules are described as effervescent granules because they contain malic acid/sodium bicarbonate effervescent couple. However, since Armitage's composition contains all components of the instant claims, it can also be used as a non-effervescent formulation with or without the malic acid/bicarbonate. It is noted that solid non-effervescent composition are preferred by Armitage et al. See, col. 4, lines 23-26. I would have been obvious to add sodium carbonate in a solid non-effervescent composition since sodium carbonate is disclosed as a suitable excipient in ibuprofen composition.

7. Armitage only fails to describe the compression characteristics of the instant compositions.

8. However, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the compression force and crushing strength by routine experimentation to formulate a commercially and therapeutically feasible composition. Claim 74, drawn to a method of enhancing the compressibility of the ibuprofen composition by adding sodium carbonate to the composition, is properly rejected for reasons set forth above as it has been shown that adding sodium carbonate would have been obvious. As to the limitation "enhancing the compressibility," it is noted that the limitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is noted that Armitage teach the use of single enantiomer, and do not teach expressly a racemic mixture. However, this would not help applicants' non-obvious arguments. As disclosed by Armitage, the (+)-ibuprofen is the active agents, and is better than the racemic mixture. Racemic mixture of ibuprofen is well known in the art. (col. 1, lines 5-24. It is well settled that Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it

has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Further, optical enantiomers or their mixture are expected to be similar in their physical and chemical properties. See In re Anthony 162 USPQ 594; In re Adamson 125 USPQ 233. As to the limitation " the dosage form does not contain any soluble acidic component with which the sodium bicarbonate could react in an effervescent reaction." It is noted that omitting an ingredient in a product so that the product would not have the properties due to that ingredient would not produce a distinct and patentable subject matter. It has been held that omission of an element and its function is obvious if the function of the element is not desired. See, MPEP 2144.04 II. In instant case, the claimed composition omits the acidic ingredient for effervescent in the prior art, and is without effervescent. Thus, the claimed composition (without effervescent) would have been obvious over the composition in Armitage.

Claims 39-47, 52-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armitage et al US Patent 5,696,165 in view of Arvanitidou et al WO 96/19982.

9. The teachings of Armitage are described above. Armitage does not explicitly that his granules can be used in as a non-effervescent formulation with the presence of sodium carbonate.

10. Arvanitidou is merely used to show that preparing a non-effervescent ibuprofen composition is well recognized in the art and readily employed to prepared ibuprofen containing compositions with the presence of sodium carbonate (see pages 5-6; page 7 last paragraph).

11. Arvanitidou teaches methods of making non-effervescent compositions comprising ibuprofen and an inorganic alkaline salt such as sodium carbonate (see page 5, last paragraph; page 9, examples I-V). Arvanitidou describes that converting the non-effervescent formulation to

an effervescent formulation merely requires the addition of an organic acid such as citric acid or malic acid (see page 7, 2nd paragraph and page 9, last 3 lines). Arvanitidou only fails to use a racemic ibuprofen salt form.

Nevertheless, it would have been further obvious to one of ordinary skill in the art at the time of invention to merely eliminate the malic acid of Armitage granules to formulate a non-effervescent solid formulation for any patient preferring non-effervescent formulations of ibuprofen. The ordinary skill in the art would have had a reasonable expectation of success, because as shown by Arvanitidou, adding an organic acid to non-effervescent formulations of Ibuprofen to convert a non-effervescent formulation to an effervescent formulation is conventional and well within purview of one of ordinary skill in the art.

Response to the Arguments

Applicants' amendments and remarks submitted March 5, 2007 have been fully considered, but are not persuasive.

As to the omission of acidic components, it is noted that omitting an ingredient in a product so that the product would not have the properties due to that ingredient would not produce a distinct and patentable subject matter. It has been held that omission of an element and its function is obvious if the function of the element is not desired. See, MPEP 2144.04 II. In instant case, the claimed composition omits the acidic ingredient for effervescent in the prior art, and is without effervescent. Thus, the claimed composition (without effervescent) would have been obvious over the composition in Armitage.

12. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Particularly, in view both Armitage et al and Arvanitidou et al, the employment of sodium carbonate in non-effervescent pharmaceutical composition is obvious.

13. In response to applicant's argument that the prior art fails to teach that sodium carbonate enhances compressibility, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Wang

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617